



SAFETY DATA SHEET

1. Identification

Product identifier	Verzenio™	
Other means of identification		
Item Code	TA6216, TA5337, TA4815, TA4483, 703137, 703138, 703139, 703140, ZD0165, ZD0166, ZD0167, ZD0169	
Recommended use	Pharmaceutical	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	Eli Lilly and Company	
Address	Lilly Corporate Center Indianapolis, IN 46285 United States	
Telephone	Phone:	+1-317-276-2000
E-mail	lilly_msds@lilly.com	
Emergency phone number	CHEMTREC:	+1-800-424-9300

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Reproductive toxicity	Category 1B
	Specific target organ toxicity, repeated exposure	Category 2
OSHA defined hazards	Not classified.	

Label elements



Signal word Danger

Hazard statement

H302	Harmful if swallowed.
H360	May damage fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.

Precautionary statement

Prevention

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response

P308 + P313	IF exposed or concerned: Get medical advice/attention.
-------------	--

Storage

Not available.

Disposal

Not available.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Abemaciclib	IUPAC Name: N-{{5-[(4-ETHYLPIPERAZIN-1-YL)METHYL]PYRIDIN-2-YL}-5-FLUORO-4-[4-FLUORO-2-METHYL-1-(1-METHYLETHYL)-1H-BENZIMIDAZOL-6-YL]PYRIMIDIN-2-AMINE	1231929-97-7	35.71

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
Skin contact	Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Ingestion	Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.
Most important symptoms/effects, acute and delayed	Harmful if swallowed. May cause reproductive effects. Prolonged exposure may cause chronic effects.
General information	The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

5. Fire-fighting measures

Suitable extinguishing media	Carbon dioxide, dry chemical or water.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Hazardous decomposition products formed under fire conditions.
Special protective equipment and precautions for firefighters	Wear self-contained breathing apparatus and protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up	The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur. Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.
Conditions for safe storage, including any incompatibilities	Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG) Components	Type	Value
Abemaciclib (CAS 1231929-97-7)	TWA (12hrs)	1.4 ug/m3

Lilly (LEG) Components	Type	Value
	TWA (8hrs)	2 ug/m3
Biological limit values	No biological exposure limits noted for the ingredient(s).	
Exposure guidelines	Health Based Excursion Limit: Maintain Full Shift TWA	
Appropriate engineering controls	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator (i.e. glove bag/glove box) and/or closed transfers to maintain airborne levels below occupational exposure level (OEL).	
Individual protection measures, such as personal protective equipment		
Eye/face protection	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.	
Skin protection		
Hand protection	Chemical resistant gloves.	
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.	
Respiratory protection	If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control exposure below the OEL.	
Thermal hazards	Not available.	
General hygiene considerations	Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material.	

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Color	Pale yellow to White.
Odor	Not available.
Odor threshold	Not available.
pH	Neutral
Melting point/freezing point	347 °F (175 °C) (Active ingredient)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	No test data available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	(Slightly soluble in water.)
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.

Viscosity	Not available.
Other information	
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing substances.
Hazardous decomposition products	Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

Acute toxicity Harmful if swallowed. (Active ingredient)

Components	Species	Test Results
Abemaciclib (CAS 1231929-97-7)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD50	Mouse	> 150 mg/kg (mortality, 4-day study)
	Rat	> 50 mg/kg (no mortality)

Skin corrosion/irritation No effects identified in animal studies. (Active ingredient)
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Bovine Corneal Opacity and Permeability assay: No eye irritation. (Active ingredient)
Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity Result in genetic toxicity assays (in vitro and in vivo): Negative (Active ingredient)
Based on available data, the classification criteria are not met.

Carcinogenicity Not listed by IARC, NTP, ACGIH or OSHA.
Due to lack of data the classification is not possible.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Animal studies have reported the following effects: Decreased fetal weight. Increased fetal malformations. (Active ingredient)

Specific target organ toxicity - single exposure No significant adverse effects reported. (Active ingredient)
Due to inconclusive data the classification criteria are not met.

Specific target organ toxicity - repeated exposure Animal studies have reported the following effects: Changes in male reproductive organs. Bone marrow changes. Blood effects (decreased red blood cell, white blood cell, and platelet counts). Kidney effects. Lymphoid tissue effects. Gastrointestinal effects. Lung effects. (Active ingredient)

Aspiration hazard Not applicable.

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Abemaciclib (CAS 1231929-97-7)			
Aquatic			
Algae	EC50	Green Algae (<i>Pseudokirchneriella subcapitata</i>)	19 µg/l, 72 h (yield and growth rate)
	LOEC	Green Algae (<i>Pseudokirchneriella subcapitata</i>)	14 µg/l, 72 h (yield and growth rate)
	NOEC	Green Algae (<i>Pseudokirchneriella subcapitata</i>)	5.9 µg/l, 72 h (yield and growth rate)
Crustacea	EC50	<i>Daphnia magna</i>	> 43000 µg/l, 48 h (acute immobilization) 130 µg/l, 21 d (chronic growth, reproduction and survival)
	LOEC	<i>Daphnia magna</i>	50 µg/l, 21 d (chronic growth, reproduction and survival)
	NOEC	<i>Daphnia magna</i>	5600 µg/l, 48 h (acute immobilization) 20 µg/l, 21 d (chronic growth, reproduction and survival)
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>)	6200 µg/l, 96 h (acute mortality)
	LOEC	Fathead minnow (<i>Pimephales promelas</i>)	170 µg/l, 4 d + 28 day post-hatch (chronic growth and survival)
	NOEC	Fathead minnow (<i>Pimephales promelas</i>)	1200 µg/l, 96 h (acute mortality) 75 µg/l, 4 d + 28 day post-hatch (chronic growth and survival)
Other	EC50	Sewage Microorganisms	> 1000000 µg/l, 3 h (respiration inhibition)
	NOEC	Sewage Microorganisms	1000000 µg/l, 3 h (respiration inhibition)
Terrestrial			
Sediment	EC50	Midge (<i>Chironomus riparius</i>)	350000 ug/kg, 28 d (chronic emergence and development rate)
	LOEC	Midge (<i>Chironomus riparius</i>)	410000 ug/kg, 28 d (chronic emergence and development rate)
	NOEC	Midge (<i>Chironomus riparius</i>)	140000 ug/kg, 28 d (chronic emergence and development rate)
Soil	EC50	Soil Microorganisms	> 970 mg/kg, 28 d (carbon and nitrogen transformation)
	LC50	Collembola (<i>Folsomia candida</i>)	> 970 mg/kg (chronic mortality and reproduction)
		Earthworm (<i>Eisenia foetida</i>)	> 970 mg/kg, 14 d (acute mortality and weight change)
	LOEC	Collembola (<i>Folsomia candida</i>)	> 970 mg/kg (chronic mortality and reproduction)
		Earthworm (<i>Eisenia foetida</i>)	970 mg/kg, 14 d (acute mortality and weight change)
	NOEC	Collembola (<i>Folsomia candida</i>)	970 mg/kg (chronic mortality and reproduction)
	Earthworm (<i>Eisenia foetida</i>)	485 mg/kg, 14 d (acute mortality and weight change)	
	Soil Microorganisms	970 mg/kg, 28 d (carbon and nitrogen transformation)	

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient n-octanol / water (log Kow)

Abemaciclib 3.61, pH 7 at 25°C
4.22, pH 9 at 25°C

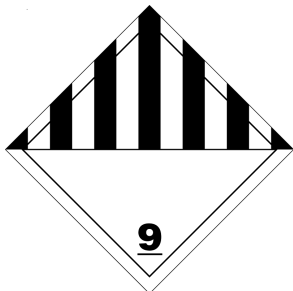
Bioconcentration factor (BCF)

Abemaciclib

181 - 240 L/KG

Mobility in soil Not available.**Other adverse effects** Not available.**13. Disposal considerations****Disposal instructions** Dispose of contents/container in accordance with local/regional/national/international regulations.**14. Transport information****DOT**

Not regulated as dangerous goods.

IATA**UN number** UN3077**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Abemaciclib)**Transport hazard class(es)****Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards** Yes**ERG Code** 9L**Special precautions for user** Not available.**Other information****Passenger and cargo aircraft** Allowed with restrictions.**Cargo aircraft only** Allowed with restrictions.**IMDG****UN number** UN3077**UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Abemaciclib)**Transport hazard class(es)****Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards****Marine pollutant** Yes**EmS** F-A, S-F**Special precautions for user** Not available.**Transport in bulk according to** Not available.**Annex II of MARPOL 73/78 and the IBC Code****IATA; IMDG****Marine pollutant**

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 09-28-2017

Version # 01

Lilly Lab Code Health: 1
Fire: 1
Reactivity: 1
Special 1: R

List of abbreviations LEG: Lilly Exposure Guideline
TWA: Time Weighted Average

Disclaimer As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Eli Lilly and Company
Hazard Communication
+1-317-651-9533

Revision information

Product and Company Identification: Alternate Trade Names

Transport Information: Material Transportation Information

Regulatory Information: Risk Phrases - Class.

Other information, including date of preparation or last revision: Disclaimer

Other information, including date of preparation or last revision: List of abbreviations